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Notice of Allowability	Application No.	Applicant(s)	
	10/051,952	WALKER, PATRICIA S.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--
 All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/12/07.
 2. ☒ The allowed claim(s) is/are 1-4, 10, 12, 36-39 and 43-48.
 3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| <ol style="list-style-type: none"> 1. <input type="checkbox"/> Notice of References Cited (PTO-892) 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | <ol style="list-style-type: none"> 5. <input type="checkbox"/> Notice of Informal Patent Application 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance 9. <input type="checkbox"/> Other _____ |
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DETAILED ACTION

Status of the Claims

1. Claims 1-4, 10, 12, 36-39 and 43-48 are pending.

Applicant's amendment filed January 12, 2007 is acknowledged, and applicants' response has been fully considered. Claims 1, 36, 45 and 46 have been amended, and a new claim 48 has been added. Therefore, claims 1-4, 10, 12, 36-39 and 43-48 are examined.

Withdrawn Claim Rejections - 35 USC § 112

2. The previous rejection of claims 1-4, 10 and 12 under 35 U. S. C. 112, second paragraph, is withdrawn in view of applicants' amendment to the claims, and applicants' response at page 4 in the amendment filed January 12, 2007.

Examiner's Amendment

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Claude L. Nassif on April 5, 2007.

Examiner's Amendment to the Specification:

Please replace the paragraph at page 1, lines 5-8 with the following paragraph:

The present application is continuation in part of application Serial No. 09/730,237 filed December 5, 2000, now abandoned, the disclosure of which is incorporated, in its entirety, herein by reference.

Examiner's Amendment to the Claims:

Claims 1 and 48 have been amended as follows:

1. (Currently amended) A method for reducing a wrinkle in a human subject, the method comprising the step of administering an amount of a botulinum toxin in powder form to the human subject effective to reduce a wrinkle ~~of a human subject~~ using a needleless syringe, thereby reducing the wrinkle.

48. (Currently amended) A method for treating a dermal wrinkle in a human subject, the method comprising the step of administering an amount of a botulinum toxin type A in powder form to the human subject effective to reduce a dermal wrinkle ~~of a human subject~~ using a needleless syringe, thereby treating the dermal wrinkle.

The following is an Examiner's Statement of Reasons for Allowance: The following references are related to the claimed invention. Borodic (U. S. Patent 5,183,462) discloses the injection of an appropriate dose of a botulinum toxin such as botulinum toxin type A to interrupt nerve impulse transmission across the neuromuscular junction and to attenuate tone of muscles about the eyes and forehead can remove wrinkles and brow furrows. Vadoud-Seyedi *et al.* (Dermatology 201, 179 (September 2000)) disclose mouse botulinum toxin A in NaCl solution is injected into patients with plantar hyperhidrosis with a Dermojet (a needleless injection system). Slate *et al.* (U.S. Patent 6,645,169) teach three types of injections may be performed by a needles injector: 1) shallow, intra-dermal injections, where the fluid medicament is infused into skin; 2) medium depth, subcutaneous injections where the fluid medicament is infused into fatty tissue beneath skin; and 3) deeper intra-muscular injections where the fluid medicament is delivered directly into muscle tissue, and depending on the type of injection that is desired and the general nature or condition of the patient's skin, the fluid pressure that is necessary to make an appropriate hole can vary from injection to injection. However, the combined references do not teach or suggest that a method for reducing a wrinkle or treating brow furrows in a human subject, comprising administering a botulinum toxin in powder form using a needleless syringe. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Bragdon can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Primary Patent Examiner



CHIH-MIN KAM
PRIMARY EXAMINER

CMK

April 5, 2007